(ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.

(2) The thirty-day period set forth in paragraph (d)(1) of this section is not extendable.

(e) The submission of a request under §1.705(c) for reinstatement of reduced patent term adjustment will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraph (c)(10) of this section.

(f) An application filed under 35 U.S.C. 111(a) is in condition for examination when the application includes a specification, including at least one claim and an abstract (§1.72(b)), and has papers in compliance with §1.52, drawings (if any) in compliance with §1.84, any English translation required by §1.52(d) or §1.57(a), a sequence listing in compliance with §1.821 through §1.825 (if applicable), the inventor's oath or declaration or an application data sheet containing the information specified in §1.63(b), the basic filing fee (§1.16(a) or §1.16(c)), the search fee (§1.16(k) or §1.16(m)), the examination fee (§1.16(o) or §1.16(q)), any certified copy of the previously filed application required by §1.57(a), and any application size fee required by the Office under §1.16(s). An international application is in condition for examination when the application has entered the national stage as defined in §1.491(b), and includes a specification, including at least one claim and an abstract (§1.72(b)), and has papers in compliance with §1.52, drawings (if any) in compliance with §1.84, a sequence listing in compliance with §1.821 through §1.825 (if applicable), the inventor's oath or declaration or an application data sheet containing the information specified in §1.63(b), the search fee (§1.492(b)), the examination fee (§1.492(c)), and any application size fee required by the Office under §1.492(j). An application shall be considered as having papers in compliance with §1.52, drawings (if any) in compliance with §1.84, and a sequence listing in compliance with §1.821 through §1.825 (if applicable) for purposes of this paragraph on the filing date of the latest reply (if any) correcting the papers, drawings, or sequence listing that is prior to the date of mailing of either an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151, whichever occurs first.

[65 FR 56393, Sept. 18, 2000, as amended at 69 FR 21711, Apr. 22, 2004; 69 FR 50002, Aug. 12, 2004; 72 FR 46843, Aug. 21, 2007; 74 FR 52691, Oct. 14, 2009; 76 FR 74702, Dec. 1, 2011; 77 FR 46628, Aug. 6, 2012; 77 FR 49360, Aug. 16, 2012; 78 FR 19420, Apr. 1, 2013; 78 FR 62408, Oct. 21, 2013; 80 FR 1356, Jan. 9, 2015]

§1.705 Patent term adjustment determination.

(a) The patent will include notification of any patent term adjustment under 35 U.S.C. 154(b).

(b) Any request for reconsideration of the patent term adjustment indicated on the patent must be by way of an application for patent term adjustment filed no later than two months from the date the patent was granted. This two-month time period may be extended under the provisions of §1.136(a). An application for patent term adjustment under this section must be accompanied by:

(1) The fee set forth in §1.18(e); and

(2) A statement of the facts involved, specifying:

(i) The correct patent term adjustment and the basis or bases under §1.702 for the adjustment;

(ii) The relevant dates as specified in §§1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in §1.703(f) to which the patent is entitled;

(iii) Whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and

(iv)(A) Any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in §1.704; or

(B) That there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing

or examination of such application as set forth in § 1.704.

(c) Any request for reinstatement of all or part of the period of adjustment reduced pursuant to § 1.704(b) for failing to reply to a rejection, objection, argument, or other request within three months of the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request must be filed prior to the issuance of the patent. This time period is not extendable. Any request for reinstatement of all or part of the period of adjustment reduced pursuant to § 1.704(b) under this paragraph must also be accompanied by:

(1) The fee set forth in § 1.18(f); and

(2) A showing to the satisfaction of the Director that, in spite of all due care, the applicant was unable to reply to the rejection, objection, argument, or other request within three months of the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request. The Office shall not grant any request for reinstatement for more than three additional months for each reply beyond three months from the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request.

(d) No submission or petition on behalf of a third party concerning patent term adjustment under 35 U.S.C. 154(b) will be considered by the Office. Any such submission or petition will be returned to the third party, or otherwise disposed of, at the convenience of the Office.

[65 FR 56394, Sept. 18, 2000, as amended at 69 FR 21711, Apr. 22, 2004; 78 FR 19420, Apr. 1, 2013]

Extension of Patent Term Due to Regulatory Review

§ 1.710 Patents subject to extension of the patent term.

(a) A patent is eligible for extension of the patent term if the patent claims a product as defined in paragraph (b) of this section, either alone or in combination with other ingredients that read on a composition that received permission for commercial marketing or use, or a method of using such a product, or a method of manufacturing such a product, and meets all other conditions and requirements of this subpart.

(b) The term *product* referred to in paragraph (a) of this section means—

(1) The active ingredient of a new human drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(2) The active ingredient of a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) that is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes including site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(3) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

[54 FR 30379, July 20, 1989]

§ 1.720 Conditions for extension of patent term.

The term of a patent may be extended if:

(a) The patent claims a product or a method of using or manufacturing a product as defined in § 1.710;

(b) The term of the patent has never been previously extended, except for extensions issued pursuant to §§ 1.701, 1.760, or § 1.790;

(c) An application for extension is submitted in compliance with § 1.740;

(d) The product has been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial marketing or use;

(e) The product has received permission for commercial marketing or use and—

(1) The permission for the commercial marketing or use of the product is the first received permission for commercial marketing or use under the